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SECTION 5, 510(k) Summary

Company Information:

Smiths Medical ASD, Inc.
10 Bowman Drive
Keene, NH 03431
(603) 352-3812, prompt 4, ext 2493
Contact: Brian D. Farias
Regulatory Affairs Manager

NOV 3 0 2007

Summary Prepared: September 28, 2007 (Revised November 21, 2007)

Product Name:

Trade Name: **Saf-T Closed Blood Collection System®**

Common Name: Venous Blood Collection Device

Classification Name: 862.1675 Blood Specimen Collection Device

Predicate Device(s):

K923090 (Ryan Medical - subsequently acquired from MPS Acacia by Smiths Medical ASD, Inc) Saf-T Holder multi sample Luer adapter with blood

K895705 (Ryan Medical - subsequently acquired from MPS Acacia by Smiths Medical ASD, Inc) Shamrock Safety Blood Collection Set

K895367 (Medical Product Specialists) Intravenous Extension Set

MPS Acacia marketed the Saf-T Closed Blood Collection System® under the trade name CVS^2 Closed Venous Blood Sample Collection System. MPS Acacia wrote a "letter to file" which identifies the above 510(k)'s and is found in attachment I.

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Device Description:

The Saf-T Closed Blood Collection System® is a venous blood drawing device that consists of three distinct configurations with distinct uses as follows.

1. REF Code 99200: Syringe line draw and transfer

This device consists of IV tubing with a male and female Luer, clamps to control blood flow, and a Saf-T Holder® Device.

- The male Luer is attached to a peripheral IV catheter hub at the time of IV catheter insertion.
- A sample syringe is attached to the female Luer to collect the blood sample.
- Transfer from the sample syringe is accomplished by inserting vacuum tubes into the Saf-T Holder® device.

2. REF Code 992XX*: Syringe draw and transfer via Saf-T Wing® access

*XX corresponds to the needle gauge, example: REF 99223 is the 23G needle

This device consists of IV tubing with a female Luer , clamps to control blood flow, a Saf-T Wing® needle and a Saf-T Holder® Device. The Saf-T Wing® needle is offered in three sizes: 21G, 23G, 25G all ¾" long.

- The vein is accessed via the Saf-T Wing® needle
- Blood is drawn into a syringe which is attached to the female Luer
- The blood sample is then transferred from the syringe by inserting vacuum tubes into the Saf-T Holder® device.

3. REF Code 99300: Syringe line draw, transfer and flush

This device consists of IV tubing with a male Luer, two female Luers , clamps to control blood flow, and a Saf-T Holder® Device.

- The male Luer is attached to a peripheral IV catheter hub at the time of IV catheter insertion.
- A sample syringe is attached to the female Luer to collect the blood sample.
- A pre-filled flush syringe is attached to the second female Luer.
- The blood sample is then transferred from the syringe by inserting vacuum tubes into the Saf-T Holder® device.
- The catheter is flushed using the attached pre-filled syringe

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Indications for Use:

REF Code 99200 and 99300

Device Name: **Saf-T Closed Blood Collection System® with Saf-T Holder® Device and Male Luer Connector**

Indications for Use:

The Saf-T Closed Blood Collection System® is attached to a peripheral IV catheter at the time of IV catheter placement to allow syringe blood draw and transfer to fill vacuum tubes.

REF Code 992XX

Device Name: **Saf-T Closed Blood Collection System® with Saf-T Holder® and Saf-T Wing® Device**

Indications for Use:

The Saf-T Closed Blood Collection System® is intended for use as syringe blood draw device and sample transfer device from a syringe to a vacuum tube.

Technological Characteristics:

The proposed and predicate devices have the same characteristics, i.e. vascular access via a peripheral IV catheter or a safety needle with tubing and clamps to control blood flow, Luers for syringe attachment and a Saf-T Holder® device for vacuum tube placement.

Non-Clinical Data:

Bench testing confirms that the proposed device and the predicate device have similar performance specifications.

Clinical Data:

Not Required

Conclusion:

The bench testing conducted demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Brian D. Farias
Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2007

Mr. Brain D. Farias
Regulatory Affairs Manager
Smiths Medical ASD, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431

Re: K072783
Trade/Device Name: REF Code 99200: Saf-T Closed Blood Collection System® with Saf-T Holder® Device and male Luer Connector

REF Code 992XX: Saf-T Closed Blood Collection System® with Saf-T Holder® and Saf-T Wing® Device

REF Code 99300: Saf-T Closed Blood Collection System® with Saf-T Holder® Device and male Luer Connector

Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: II
Product Code: JKA
Dated: September 28, 2007
Received: October 2, 2007

Dear Mr. Farias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): K072783

REF Code 99200 and 99300
Device Name: **Saf-T Closed Blood Collection System® with Saf-T Holder® Device and Male Luer Connector**

Indications for Use:
The Saf-T Closed Blood Collection System® is attached to a peripheral IV catheter at the time of IV catheter placement to allow syringe blood draw and transfer to fill vacuum tubes.

REF Code 992XX
Device Name: **Saf-T Closed Blood Collection System® with Saf-T Holder® and Saf-T Wing® Device**

Indications for Use:
The Saf-T Closed Blood Collection System® is intended for use as syringe blood draw device and sample transfer device from a syringe to a vacuum tube.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072783